

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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)	
UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	
)	
v.)	No. 20-cv-11548-NMG
)	
TEVA PHARMACEUTICALS USA, INC., and)	
TEVA NEUROSCIENCE, INC.,)	
)	
Defendants.		

JOINT STATUS REPORT

In advance of the November 30, 2021 scheduling conference, Plaintiff United States of America (“United States”) and Defendants Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc. (together, “Teva”) submit this Joint Status Report to inform the Court of an issue that requires a judicial resolution.

The parties agree on the need for a protective order. On September 29, 2021, the United States provided Teva with a proposed Confidentiality Agreement and Protective Order (“the Agreement”). Over the last seven weeks, counsel for the United States and for Teva have conferred and agree on all provisions of the Agreement, with one exception. That sole disagreement relates to Paragraph 3(a), which addresses how documents produced prior to the litigation should be designated as confidential under the Agreement. In particular, the parties disagree on how the Agreement should address the confidentiality designation of documents that Teva and third parties produced to the United States during the pre-suit investigation. Teva, for example, marked its entire production of over 120,000 documents as “Confidential-FOIA Exempt,” as Teva’s counsel contends is customary in a HIPAA subpoena response. Third parties including the Chronic

Disease Fund, the Assistance Fund, AssistRx, and Advanced Care Scripts, also produced documents as confidential to the United States during its investigation. Teva seeks to maintain the confidentiality designation of all documents produced pre-litigation until a later stage in the litigation. The United States proposes that Teva and third parties must affirmatively designate any document as confidential for the protective order to apply, except for documents post-dating December 31, 2017, within sixty days of the entry of the Agreement or lose confidentiality protection for those documents. Attached as Exhibit 1 is the United States' proposed Agreement, and Exhibit 2 is a redline that shows Teva's proposal. The parties' positions are set forth more fully below:

The United States' Position

The government's position is that blanket confidentiality designations are inappropriate, unnecessarily burdensome to the parties and the Court, and do not serve the public's interest in the transparent administration of justice. Under the government's proposal, previously-produced documents dated before January 1, 2018, would not be treated as confidential unless Teva or the producing party affirmatively redesignated them as such in good faith. The government does not believe that these dated documents, some of which are over ten years old, qualify as confidential commercial information. Despite repeated government requests, counsel for Teva has yet to identify a single document it believes qualifies. The government's approach would (i) streamline discovery by minimizing future disputes regarding confidentiality and sealed filings; and (ii) result in a narrowly tailored protective order that weighs the public's strong interest in disclosure against Teva's confidentiality concerns.

"Access to judicial records and documents allows the citizenry to monitor the functioning of our courts, thereby insuring quality, honesty and respect for our legal system." *United States*

v. Kravetz, 706 F.3d 47, 56–57 (1st Cir. 2013) (internal quotation marks omitted). Although Rule 26(c) permits courts to enter protective orders, “[p]rotective orders should be narrowly tailored and entered only after a party sets forth good cause based up[on] a particular demonstration of facts.” *Suture Exp., Inc. v. Cardinal Health, 200, LLC*, No. 12-2760-RDR, 2013 WL 6909158, at *5 (D. Kan. Dec. 31, 2013); *see also In re BofI Holding, Inc. Sec. Litig.*, 318 F.R.D. 129, 133 (S.D. Cal. 2016) (“Any protective order that is issued must be narrowly tailored and cannot be overbroad.”); *Zenith Radio Corp. v. Matsushita Elec. Indus. Co.*, 529 F. Supp. 866, 892 (E.D. Pa. 1981) (“[A] protective order should always be narrowly drawn.”). To that end, the rule permits the use of protective orders to protect “trade secret[s] or other confidential research, development, or commercial information.” Fed. R. Civ. P. 26(c)(1)(G). Commercial information subject to protection typically includes “business information that might harm a litigant’s competitive standing.” *Bradford & Bigelow, Inc. v. Richardson*, 109 F. Supp. 3d 445, 448 (D. Mass. 2015) (quoting *Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 598 (1978)).

The government’s approach properly places the burden on Teva to identify the few pre-2018 documents in its production that may contain confidential commercial information.¹ As

¹ The case Teva cites for the proposition that the Government’s proposal is “unfair, inconvenient, and costly” undermines its position. *See Graco, Inc. v. PMC Glob., Inc.*, No. 08-1304 (FLW), 2009 WL 10742142, at *1, *2 (D.N.J. Oct. 23, 2009). In *Graco*, the court had previously entered a “Stipulated Protective Order” and the plaintiff in that case designated trade secret materials as “Attorneys’ Eyes Only,” consistent with the terms of that protective order. The defendants, which were plaintiff’s “direct competitors,” sought a “wholesale modification” of the terms of the protective order to de-designate those documents, without following the established protocol for re-designation of documents under the protective order. Unlike Teva, the plaintiff in that case identified specific documents deserving of confidential treatment under a stipulated agreement, and identified particular potential harms pertaining to the treatment of those documents—that Defendants’ request would provide “unfettered and unlimited access to [plaintiff’s] most sensitive information and documents to Defendants – all of whom are [plaintiff’s] direct competitors and against whom there is now direct evidence of

Judge Saylor noted in *United States v. Regeneron Pharmaceuticals, Inc.*, No. 1:20-cv-11217 (D. Mass. June 24, 2020), a case involving similar allegations and a nearly identical dispute related to the parties' protective order:

[W]hen you over-designate things or you designate everything [] you have this awkward and cumbersome system where all kinds of things are filed under seal. And, you know, then there are motions to unseal things and disputes about it.

...

So my presumptive view here is that Regeneron as the company seeking to designate something as confidential has the burden of doing so. And if it thinks that this is sufficiently important, you know, it ought to devote the resources to going through and making those designations.

...

This ought to be, to the extent possible, a public proceeding, taking into account that there are other values that need to be protected, including genuine business information. So, you know, if there really are things from 2015 and earlier that's now more than six years old but that remain confidential, you know, let's talk, or you all should talk about, well, what are they? What do you really care about? You know, let's get specific. Either you have a specific concern or you don't. If it's just a generalized concern, it's hard for me to give it much credence, and that ought to at least focus the process a little bit.

Ex. 3, Mar. 4 Hr'g Tr. at 15:10-14, 15:24-16:3, 16:18-17:3. Teva, by contrast, marked as confidential *all* of the over 120,000 documents it has produced to date, including *publicly-available* documents, such as news articles. *See, e.g.* Ex. 4, Tev_167401 (e-mail from third party to Teva consisting of a Barron's news article); Ex. 5, Tev_007249 (Bloomberg news article); Ex. 6, Tev_307715 (e-mail between Teva and third party containing internet blog post); Ex. 7, Tev_167187 (e-mail between Teva and third party consisting of forwarded New York Times

misappropriation.” In contrast, Teva has not identified any specific documents containing confidential commercial information, nor has it identified any harms associated with any potential treatment of the dated documents at issue, and it has not conducted any confidentiality or designation review to date.

article link). Teva's proposal to retain its prior confidentiality "designations" is therefore an improper attempt to assert broad confidentiality with no effort to ensure its designations are appropriate, and its approach requires the parties to engage in cumbersome and costly negotiations or motions practice. The Court and the government should not be forced to expend time and resources in this manner, especially where Teva put forth no effort to properly designate its own documents in the first instance.

Mass, indiscriminate, or routinized designations are prohibited under Fed. R. Civ. P. 26. For example, the court in *Dershowitz v. Cable News Network, Inc.*, 0:20-cv-61872 (S.D. Fla.) recently included the following language in the protective order, over defendant's objections:

The Parties understand that violations of this Order may result in contempt proceedings and/or monetary sanctions pursuant to applicable law, including Rule 37 of the Federal Rules of Civil Procedure. **The parties further understand that mass, indiscriminate, or routinized designations are prohibited.** Designations that are shown to be clearly unjustified, frivolous or that have been made for an improper purpose (e.g., to unnecessarily encumber the case development process or to impose unnecessary expenses and burdens on other parties) may expose the Designating Party to sanctions pursuant to the Federal Rules of Civil Procedure, including Rule 37, unless a correction to the designation is made during the meet and confer process contained in this order.

Id. Dkt. 47 & 48 (emphasis added).

Moreover, the age and content of the documents at issue cast serious doubt on *any* claim of confidentiality, let alone a claim of blanket confidentiality for *all of them*. The vast majority of Teva's documents relate to its (i) conduct in providing patient assistance; and (ii) sales and distribution practices for its multiple sclerosis drug Copaxone. With respect to the former, it is unclear how Teva's decision-making concerning its purported "donations" to patient assistance charities constitutes confidential commercial information. Further, Teva has stopped making payments to The Assistance Fund, Inc. ("TAF"), Chronic Disease Fund, Inc. ("CDF"), and Advanced Care Scripts, Inc. ("ACS"). All three of those entities have entered into public False

Claims Act settlements with the government relating to violations of the Anti-Kickback Statute resulting from copay assistance to Medicare patients, undermining any suggestion that Teva's alleged practices were trade secrets or otherwise confidential.² With respect to the latter, Teva's Copaxone practices have changed drastically since 2017. All formulations of Copaxone now have generic competition. And Teva sold its patient services division for Copaxone in 2018.³ Nonetheless, should Teva identify previously-produced documents that it believes are confidential, the government's proposal would, of course, permit the protective order to apply to those documents. The same principle would apply to documents produced by any third parties.

Notably, at least two other courts in this district have adopted the government's proposed approach. The courts in both *United States v. Regeneron* and *United States ex rel. Kieff v. Wyeth*, No. 1:03-cv-12366-DPW (D. Mass. Jan. 10, 2011), both of which were False Claims Act cases involving a large pharmaceutical company, entered protective orders in which all documents the defendant produced prior to the litigation were presumptively non-confidential absent affirmative redesignation of specific documents. *See Wyeth*, ECF No. 215 at 3;

² The settlements are available here:

ACS: <https://www.justice.gov/usao-ma/pr/specialty-pharmacy-advanced-care-scripts-agrees-pay-35-million-resolve-allegations-it>

CDF: <https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicare>

TAF: <https://www.justice.gov/usao-ma/pr/third-foundation-resolves-allegations-it-conspired-pharmaceutical-companies-pay-kickbacks>

³ Elise Reuter, *AssistRx co-founder: Why company took on Teva employees, lease in OP*, Kansas City Business Journal (April 9, 2018) (available at <https://www.bizjournals.com/kansascity/news/2018/04/09/assistrx-co-founder-why-company-took-on-teva.html>)

Regeneron, ECF No. 54 at 3. The government respectfully requests that this court take the same approach.

Finally, the government's position is consistent with an expeditious discovery schedule. The United States is prepared to provide responsive documents and does not believe that discovery should be bogged down by unnecessary confidentiality arguments. The documents at issue do not appear to be confidential—and if they are, Teva is responsible for making those designations. The Court should decline Teva's attempt to drag the government and the Court into disputes over its blanket confidentiality designations. If Teva believes it has confidential information to protect, it must spend the time and resources itself to identify it.

Teva's Position

The United States' position with respect to Paragraph 3(a) is impeding the flow of discovery in this case and threatens Teva and the producing third parties with the Hobson's choice of either an enormous and unnecessary burden or the waiver of confidentiality protection for thousands of documents. The United States' proposal is both unfair, inconvenient, and costly, and also runs contrary to the United States' stated desire to "move the parties to trial as expeditiously as possible, while also providing an adequate opportunity for discovery." Dkt. 36 at 2. Teva's proposal, on the other hand, ensures efficiency by leaving the current confidentiality designations undisturbed and instead would address any confidentiality concerns before Court filings and trial through the standard sealing and re-designation process that the Agreement already contemplates. Thus, rather than re-review hundreds of thousands of documents, the parties would simply meet and confer regarding the limited set of documents that are likely to be submitted to the Court.

Federal Rule of Civil Procedure 26(c)(1) gives district courts authority to guard against discovery requests presenting "undue burden or expense" if it finds "good cause" to do so. FED.

R. Civ. P. 26(c)(1)(G); *see also* *Wilson v. Pharmerica Corp. Long Term Disability Plan*, No. 14-cv-12345-LTS, 2015 WL 4572833, at *1, *2 (D. Mass. July 29, 2015). The United States Court of Appeals for the First Circuit affords “great deference . . . to the district judge” to decide when discovery requests may cause “undue burden” to a party. *See Poliquin v. Garden Way, Inc.*, 989 F.2d 527, 532 (1st Cir. 1993). To determine whether “good cause” exists to afford discovery protections, courts balance numerous competing interests, including “the burden of producing the sought-after material.” *Metris U.S.A, Inc. v. Faro Techs., Inc.*, No. 08-11187-PBS, 2009 WL 10-694075, at *1, *3 (D. Mass. Dec. 8, 2009) (quoting *Burka v. HHS*, 87 F.3d 508, 517 (D.C. Cir. 1996)). For example, courts may refuse to modify preexisting confidentiality designations if a party requests modification merely as a matter of convenience, and the re-designation process is “unfair, inconvenient, and costly” to the opposing party. *See, e.g., Graco, Inc. v. PMC Glob., Inc.*, No. 08-1304 (FLW), 2009 WL 10742142, at *1, *2 (D.N.J. Oct. 23, 2009).⁴

There is good cause to reject the United States’ proposal that Teva and third parties re-designate their pre-litigation productions. First, the United States’ request would subject Teva to an extremely burdensome re-review of 120,000 already-produced documents and distract resources from litigating the merits of the case. The wastefulness of this effort is made clear because only a sliver of the 120,000 documents in question will likely be relied upon. *See* Ex. 3, Tr. at 4:6-4:8 (“Many of those documents we think are not relevant or probably not relevant to this case. . . .”). The United States asserts, without any basis, that discovery should not be bogged down by confidentiality arguments. Whatever concern that the United States has with respect to

⁴ The United States’ attempt to distinguish *Graco* fails. The United States argues that Teva—unlike the plaintiff in *Graco*—“has not identified any specific documents containing confidential commercial information.” *See supra* n.1. That misses the point. Teva’s primary objection is the burden of going through and identifying the specific documents containing confidential information from the thousands of documents that have already been produced.

confidentiality disputes pales in comparison to the burden associated with reviewing thousands of documents that may never be used.

Second, Teva’s proposed language eliminates the need for third parties—which complied with the United States’ pre-litigation investigation—to re-review documents and spend exorbitant amounts of time, money, and effort to avoid losing their protected status, which could unnecessarily delay Teva’s receipt of relevant discovery.⁵

The United States, to the contrary, continues to rest on the same position it did in its ongoing litigation with Regeneron without fully considering the implications of forcing third parties to re-review thousands of documents identified as confidential during the investigation. *See generally* Ex. 3. Teva recognizes that the United States’ request leaves non-parties related to the current litigation with no choice but to spend significant amounts of time and money reviewing documents or waive confidentiality protections. Moreover, this re-review could further unreasonably delay Teva’s receipt of discoverable information. While Teva’s proposed language keeps these considerations in mind, the United States’ approach does not.

For these reasons, Teva respectfully requests that this Court approve its proposed language for the Agreement’s Paragraph 3(a).

⁵ Federal Rule of Civil Procedure 45 is instructive here. Rule 45 protects non-parties from discovery when “the burden or expense of the proposed discovery outweighs its likely benefit.” *United Therapeutics Corp. v. Watson Laboratories, Inc.*, 200 F. Supp. 3d 272, 277 (D. Mass. 2016) (quoting Fed. R. Civ. P. 26(b)(1)). Traditional discovery principles under Rule 26(b)(1) apply to non-parties under Rule 45, and “the information sought must be . . . proportional to the needs to the case.” *Smith v. Turbocombustor Tech., Inc.*, 338 F.R.D. 174, 176 (D. Mass. 2021).

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Respectfully submitted,

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